Mr. Anthony Britten, SRRD Document Processing Desk (7504C) Office of Pesticide Programs U.S. Environmental Protection Agency Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, Virginia 22202

Dear Mr. Britten,

Re: Carbaryl; Chemical number 56801; EPA Reg. No. 264-324 Error Correction of Carbaryl Risk Assessments

Attached are our comments on the error correction review of the revised HED and EFED Risk Assessments for Carbaryl. We have also included some comments on certain supporting documents for the HED Chapter.

One issue of concern was noted during our review of the risk assessments. It appears that the Agency intends to include the Data Evaluation Records (DERs) for a number of carbaryl studies in the draft EFED Chapter which will be made available to the public for the 60-day comment period. We believe that it is inappropriate to include the DERs in the RED document. A sufficiently detailed summary of study findings is already provided in the EFED Chapter. The summary of endpoints that is included in the draft Carbaryl EFED Chapter is typical of other Draft EFED REDs that have been issued recently and provides sufficient information to allow the reader to determine the endpoints that were selected for modeling and the justification for their selection. The inclusion of the more detailed information present in the DERs is unnecessary.

We have reviewed the dockets for many of the RED documents that have recently been issued (many other insecticides and several fungicides) and none of them include DERs in any of the preliminary Environmental Fate and Effects Assessments. DERs should be made available to the public through the regular procedure under the Freedom of Information Act after they have been reviewed and cleared for confidential business information. The inclusion of the DERs in the docket that is publicly available circumvents this process and is a departure from the procedures that have been followed until now by the Agency. It is unclear why the Agency chose to change their policy for only certain DERs for a single product when adequate summary information is already provided in the text of the Carbaryl EFED Chapter.

This issue deserves careful consideration before the Agency makes the decision to amend their existing policy on providing this type of information to the public. Your help in ensuring that

July 12, 2002 Mr. Anthony Britten Page 2 of 2

accepted procedures are followed for the public review of the Carbaryl RED Chapters is greatly appreciated.

Sincerely,

Danielle A. Larochelle Registration Manager

Corr. # daL018-02

PC Code No. 056801; Case 0080

Human Health Risk Assessment and Supporting Documents

- Phase 1 Error Correction -

July 12, 2002

Aventis CropScience P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709

Human Health Risk Assessment and **Supporting Documents**

- Phase 1 Error Correction -

TABLE OF CONTENTS

TABLE OF CONTENTS	2
HUMAN HEALTH RISK ASSESSMENT, JUNE 7, 2002	. 3
General	. 3
1.0 Executive Summary	
Dietary Risk Estimates	
Aggregate Risks and DWLOCs	
Issues for Considerations	
4.0 Non-Occupational Risk Assessment and Characterization	4
4.1 Summary of Registered Uses	
4.2 Dietary Risk Assessment	
4.3 Estimated Environmental Concentrations in Water	. 5
4.3.1 Environmental Fate Characteristics	5
4.4 Residential Risk Assessment	
4.4.2.2 Residential Handler Cancer Risks	
4.4.3 Residential Postapplication Risk Assessment	6
5.0 Aggregate Risk Assessments and Risk Characterization	
5.1 Calculation of Aggregate Risks and DWLOCs	
5.7 Summary of Aggregate Risks	. 7
7.1 Occupational Handler Risk Assessment	. 8
REVISED PRODUCT AND RESIDUE CHEMISTRY CHAPTERS FOR THE	
REREGISTRATION ELIGIBILITY DECISION; MAY 30, 2002	9
General	O
Product Chemistry Chapter of the RED Document	
Manufacturing-Use Products	
Residue Chemistry Chapter of the RED Document	
Regulatory Background	
Summary of Science Findings	
GLN 860.1200: Directions for Use	
GLN 860.1380: Storage Stability Data - Plants	
GLN 860.1500: Crop Field Trials	
GLN 860.1520: Processed Food/Feed	
GLN 860.1480: Meat, Milk, Poultry, Eggs	
Tolerance Reassessment Summary	
Table C. Tolerance Reassessment Summary for Carbaryl	12
Miscellaneous Typographical Errors	

Human Health Risk Assessment, June 7, 2002

General

Several References Throughout the Document

EPA statement:

The company name of the registrant is listed throughout the document as Aventis Corporation, Aventis Crop Sciences, Aventis Crop Science, and Aventis Crop Science Corporation.

Aventis' comment:

Reference should be either to Aventis or Aventis CropScience.

1.0 Executive Summary

Dietary Risk Estimates

Page 7; Paragraph 3; Lines 4-6

EPA statement:

"In livestock commodities, carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, 5-methoxy-6-dydroxy carbaryl and all residues which can be hydrolyzed to carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, 5-methoxy-6-hydroxy carbaryl under acidic conditions"

Aventis' comment:

Add "and" before "5-methoxy-6-hydroxy carbaryl under acidic conditions".

Aggregate Risks and DWLOCs

Page 11; Paragraph 4; Lines 9-14

EPA statement:

"Additionally, acute dietary risks were also exceeded for infants and children (1 to 6 years old) at the 99.9th percentile when the Carbamate Market Basket Survey (CMBS) was not considered in the assessment (133% of aPAD). However, the risk picture could substantively change if residential risks are refined based on updated use information from the carbaryl use survey yet to be submitted to the Agency, and the Agency uses the CMBS data even with the caveats associated with that study."

Aventis' comment:

This statement is inconsistent with information presented elsewhere in the HED Chapter. As written, the statement implies that the Agency has not yet approved the use of the CMBS data in the dietary risk assessment for carbaryl. However, EPA states in the Hazard Characterization section of the Executive Summary, page 6, paragraph 2, line 9, "Dietary exposures were calculated using FDA and PDP monitoring data, a carbamate market basket survey, and ..." which indicates that the EPA approved the use of the CMBS data. In addition, it is stated on pages 8 and 31 (Footnotes) and page 37, first paragraph: "At the present time, information from the industry-sponsored Carbamate Market Basket Survey has been approved for use in

dietary risk assessments with appropriate characterization of uncertainties associated with the conduct of the study. Hence, the use of these data in this assessment should be considered with associated caveats ..."

Issues for Considerations

Page 16, Paragraph 1, Lines 19-26

EPA statement:

It should also be noted that Aventis Crop Sciences is in the process of conducting biological monitoring studies in residences where there have been carbaryl applications (sampling urine from children) and also for field workers during harvesting and hand thinning operations in apples and cherries. Preliminary results from these studies, based on personal communication with Aventis scientists (they have not been submitted to the Agency yet), indicate body burden levels similar to those calculated by the Agency for risk assessment purposes. For example, the turf risk assessments completed by the Agency are intended to provide upper percentile exposures. The data from the monitored children appear to indicate similar results a the upper percentiles.

Aventis' comment:

This statement does not accurately reflect the true scope of the study and would be misleading. The comment would be more accurate as follows:

"It should also be noted that Aventis CropScience has completed and is in the process of submitting to the Agency a biomonitoring study of individuals in residences following the application by a member of the household to the lawn and either the vegetable garden or ornamental flowers. A biomonitoring study of for field workers during harvesting and hand thinning operations in apples and cherries will also be submitted to the Agency. Based on personal communication with Aventis scientists, preliminary results from the residential biomonitoring study indicate that the highest percentiles of the distribution of the younger children in the homes were similar to those predicted in the Agency's turf risk assessment for toddlers that are intended to represent the higher percentiles of the exposure distribution."

4.0 Non-Occupational Risk Assessment and Characterization

4.1 Summary of Registered Uses

Page 28; Table 3: Technical and Manufacturing Carbaryl Products

Aventis' comment:

Carbaryl – Technical Products

- EPA Registration No. 45735-24 (99%), Carbaryl 99% Technical Grade Insecticide, Burlington Scientific Corporation, should be added to the list of registered carbaryl technical.
- EPA Registration No. 264-325 (97.5%), Aventis CropScience, should be included in the list of manufacturing-use products.

Carbaryl – Manufacturing-Use Products

- EPA Registration No. 5481-190 (46% FI), AMVAC Chemical corporation, is an active registration and should be added to the list of Manufacturing-Use Products. (It is listed in Table 1, page 2, of the Product and Residue Chemistry Chapters)
- EPA Registration No. 4816-270 (97.5%) is no longer active; it was transferred to EPA Registration No. 432-982 (97.5%), Aventis Environmental Science USA LP, on February 22, 2000.
- EPA Registration No. 4816-407 (1%) is no longer active; it was transferred to Reg. No. 432-1006 on February 22, 2000 and subsequently transferred to Reg. No. 73049-238, Valent Bioscience Corporation, on June 27, 2001 (neither 4816-407 or 432-1006 are active).
- As stated above, EPA Registration No. 264-325 (97.5%), Aventis CropScience, should be added to the list of manufacturing-use products.

4.2 Dietary Risk Assessment

Page 31; Paragraph 1; Lines 3-5

EPA statement:

Carbaryl is used late in the season at maximal seasonal rates of 6-12 lb ai/acre. [Note: A Special Local Needs registration in California uses 16 lb ai/acre as a maximum rate on citrus.]

Aventis' comment:

The **Section 3 registration** of carbaryl products cover the use on citrus at the rate of 5-16 lbs ai/acre *in the state of California only*.

4.3 Estimated Environmental Concentrations in Water 4.3.1 Environmental Fate Characteristics

Section 4.3.1, Pages 39-40

Aventis' comment:

The text in section 4.3.1 does not include the revisions that were made to the EFED draft Chapter and is inconsistent. For example:

- on Page 39, first paragraph of Section 4.3.1, first sentence "Carbaryl and its degradate 1-naphthol are fairly mobile but are not likely to persist or accumulate in the environment."
- on Page 40, Paragraph 1, last sentence "Carbaryl is mobile to very mobile in the environment ($K_f = 1.7$ to 3.2)."

The information in the EFED chapter has been revised to

- "Carbaryl is considered to be *moderately mobile* in soils" and the K_f range is 1.7 to 3.5 (EFED Chapter, Page 20 Table 3; Page 22 Mobility).
- "... literature information suggest that it [1-naphthol] is *less persistent and less mobile* than parent carbaryl.""(EFED Chapter, Page 26, 1-Naphthol Fate and Transport).

Section 4.3.1, Paragraphs 2 and 3 (pages 39-40)

EPA statement:

In these 2 paragraphs, the chemical name for the major carbaryl degradation product is typed as "1-napthol".

Aventis' comment:

Correct spelling is "1-naphthol".

4.4 Residential Risk Assessment

4.4.2.2 Residential Handler Cancer Risks

Page 52; Paragraph 1; Lines 11-12

EPA statement:

"...[Note: Scenarios where risks are still of concern (i.e., $<1x10^{-6}$) are highlighted in the table.].

Aventis' comment:

(i.e., "<"1x10⁻⁶) should be corrected to (i.e., ">"1x10⁻⁶).

4.4.3 Residential Postapplication Risk Assessment

Page 59; Paragraph 1; Lines 4-6

EPA statement:

These levels were The Agency instead considers them a qualitative indicator that exposures in the general population are likely to occur.

Aventis' comment:

Words are missing from the first part of the sentence.

Page: 59 Paragraph: 2 Lines: 1-6

EPA statement:

Aventis Crop Science is in the process of conducting a biomonitoring study with children who live in households where carbaryl has been used. Based on discussions with Aventis, the preliminary results indicate that levels at the highest percentiles of the distribution are similar to those predicted in the Agency's turf risk assessment for toddlers which are intended to represent the higher percentiles of the exposure distribution. A more detailed analysis will be completed upon submission

Aventis' comment:

The statement does not accurately reflect the true scope of the study and would be misleading. The comment would be more accurate as follows:

Aventis CropScience has completed and is in the process of submitting to the Agency a biomonitoring study of individuals in residences following the application by a member of the household to the lawn and either the vegetable garden or ornamental flowers. Based on discussions with Aventis, preliminary results indicate that the highest percentiles of the distribution of the younger children in the homes were similar to those predicted in the Agency's turf risk assessment for toddlers that are

intended to represent the higher percentiles of the exposure distribution. A more detailed analysis will be completed upon submission.

5.0 Aggregate Risk Assessments and Risk Characterization

5.1 Calculation of Aggregate Risks and DWLOCs

Page 72; Paragraph 2; Lines 6-11

EPA statement:

"Additionally, acute dietary risks were also exceeded for infants and children (1 to 6 years old) at the 99.9th percentile when the Carbamate Market Basket Survey (CMBS) was not considered in the assessment. However, the risk picture could substantively change if residential risks are refined based on updated use information from the carbaryl use survey yet to be submitted to the Agency *and the Agency chooses to regulate using the results of the CMBS*."

Aventis' comment:

This statement is inconsistent with information presented elsewhere in the HED Chapter. As written, the statement implies that the Agency has not yet approved the use of the CMBS data in the dietary risk assessment for carbaryl. However, EPA states in the Hazard Characterization section of the Executive Summary, page 6, paragraph 2, line 9, "Dietary exposures were calculated using FDA and PDP monitoring data, a carbamate market basket survey, and ..." which indicates that the EPA approved the use of the CMBS data. In addition, it is stated on pages 8 and 31 (Footnotes) and page 37, first paragraph: "At the present time, information from the industry-sponsored Carbamate Market Basket Survey has been approved for use in dietary risk assessments with appropriate characterization of uncertainties associated with the conduct of the study. Hence, the use of these data in this assessment should be considered with associated caveats ..."

5.7 Summary of Aggregate Risks

Page 76; Paragraph 2; Lines 3-4 continued on page 77

EPA statement:

"Additionally, acute dietary risks were also exceeded for infants and children (1 to 6 years old) at the 99.9th percentile when the Carbamate Market Basket Survey (CMBS) was not considered in the assessment. However, the risk picture could substantively change if residential risks are refined based on updated use information from the carbaryl use survey yet to be submitted to the Agency *and the Agency chooses to regulate using the results of the CMBS*."

Aventis' comment:

This statement is inconsistent with information presented elsewhere in the HED Chapter. As written, the statement implies that the Agency has not yet approved the use of the CMBS data in the dietary risk assessment for carbaryl. However, EPA states in the Hazard Characterization section of the Executive Summary, page 6,

paragraph 2, line 9, "Dietary exposures were calculated using FDA and PDP monitoring data, a carbamate market basket survey, and ..." which indicates that the EPA approved the use of the CMBS data. In addition, it is stated on pages 8 and 31 (Footnotes) and page 37, first paragraph: "At the present time, information from the industry-sponsored Carbamate Market Basket Survey has been approved for use in dietary risk assessments with appropriate characterization of uncertainties associated with the conduct of the study. Hence, the use of these data in this assessment should be considered with associated caveats ..."

7.1 Occupational Handler Risk Assessment

Page: 83; Paragraph 5; Lines 9-10 and Footnote

EPA statement:

There are no data compensation issues with any of these data. ¹¹.

(Footnote) ¹¹ Non-ORETF data included in MRIDs 451672-01 and 452507-01 were from studies submitted by Aventis CropScience. The propoxur trigger sprayer study has a signed PHED data waiver but has not been included into PHED.

Aventis' comment:

Aventis concurs that there are no data compensation issues. However, the rationale presented for the propoxur trigger sprayer study is not accurate. The PHED data waiver is applicable only when the data are in PHED and not when cited outside of PHED. The propoxur study does not trigger data compensation because the study is the property of Bayer CropScience which has recently acquired Aventis CropScience.

Revised Product and Residue chemistry Chapters for the Reregistration Eligibility Decision; May 30, 2002

General

Several References Throughout the Document

EPA statement:

The company name of the registrant is listed throughout the document as Aventis Ag Company.

Aventis' comment:

Reference should be to Aventis CropScience.

Product Chemistry Chapter of the RED Document Manufacturing-Use Products

Page 2; Table 1 – Registered Carbaryl Manufacturing-Use Products

Aventis' comment:

- EPA Registration No. 45735-24 (99%), Carbaryl 99% Technical Grade Insecticide, Burlington Scientific Corporation, should be added to the list of registered carbaryl technical.
- EPA Registration No. 4816-270 (97.5%) is no longer active; it was transferred to EPA Registration No. 432-982 (97.5%), Aventis Environmental Science USA LP, on February 22, 2000.
- EPA Registration No. 4816-407 (1%) is no longer active; it was transferred to Reg. No. 432-1006 on February 22, 2000 and subsequently transferred to Reg. No. 73049-238, Valent Bioscience Corporation, on June 27, 2001 (neither 4816-407 or 432-1006 are active).
- The name of the registrant for EPA Registration No. 769-971 is Value Gardens Supply, LLC.

Corresponding corrections should be made to the Product Chemistry Section of the Memorandum for this Chapter and in other sections of the Product Chemistry Chapter of the Reregistration Eligibility Decision (RED) Document.

Residue Chemistry Chapter of the RED Document

Several References Throughout the Document

EPA statement:

The company name of the registrant is listed throughout the document as Aventis Ag Company, Aventis Ag Co., and Aventis Crop Science.

Aventis' comment:

Reference should be to Aventis CropScience.

Regulatory Background

Page 2; Paragraph 2; Line 5

EPA statement:

"... but should **not** delay on the reregistration eligibility decisions for carbaryl."

Aventis' comment:

Remove "on" from the sentence . "... but should not delay on the reregistration ..."

Summary of Science Findings

GLN 860.1200: Directions for Use

Page 3; Table A1. Carbaryl EPs with Food/Feed Uses Registered to Aventis Ag Company EPA statement:

EPA Registration No. 264-430 is listed in this table.

Aventis' comment:

The registration of SEVIN® brand Granular Carbaryl Insecticide For Outdoor Home Use, EPA Registration No. 264-430, was transferred to Aventis Environmental Science, EPA Registration No. 432-885 on February 9, 2000.

GLN 860.1380: Storage Stability Data - Plants

Page 6; Paragraph 1; Lines 2-3

EPA statement:

Additional data are required depicting the storage stability of carbaryl *per se* in an oilseed, processed commodities of an oily crop, **and a dried fruit stored for up to 10 months**.

Aventis' comment:

Inconsistencies are noted between the information presented in the section "Summary of Science Findings" and Table B. Residue Chemistry Science Assessments for Reregistration of Carbaryl (page 63)

Paragraph 1 of the "GLN 860.1380: Storage Stability Data – Plants" section indicates the need for storage stability data for dried fruit (in addition to other items). Table B data requirements (page 63 along with footnote #14 on page 73) does not request storage stability data for dried fruit; neither does the 4th paragraph on page 6 (GLN 860.1380).

GLN 860.1500: Crop Field Trials

Page 7; Paragraph 5

EPA statement:

"In addition, conclusions regarding the adequacy of the data for alfalfa, **apples**, potatoes ... are contingent upon receipt and acceptance of adequate supporting storage stability data."

Aventis' comment:

The statement is inconsistent with information elsewhere in the document. There is no requirement for storage stability data on apples in the "GLN 860.1380: Storage Stability Data – Plants" section (page 6) nor in Table B (page 63 along with footnote #14 on page 73).

Page 8; Paragraph 14; Line 4

EPA statement:

"However, additional residue data are required if the registrant seeks tolerances for residues in/on succulent, shelled pea and bean commodities." (Also stated in the Memorandum on page 3, paragraph 3).

Aventis' comment:

This statement is in contradiction with paragraph 6 of this section: "... adequate magnitude of the residue data are available on the following crops:beans (dried and succulent), ... peas (dried and succulent" and Table B requirements for crop field trials (page 65). Also, MRID 43984701 (succulent bean) and MRID 43703102 (Fresh pea) were found to be acceptable.

GLN 860.1520: Processed Food/Feed

Page 9; Paragraph 1; Lines 4-6

EPA statement:

Based on the available processing studies, tolerances are required for residues in citrus fruit oil, **raisins**, **wet apple pomace**, and rice hulls only.

Aventis' comment:

EPA requests processed commodity tolerances for (among other commodities) wet apple pomace and raisins (see also Table C, page 85). Calculations according to the 860.1520 Guidelines indicates that processed commodity tolerances are not needed for these commodities. The Agency's statement appears to be the result of a mathematical or computational type error since the 860.1520 Guidelines are rather clear on determination of need for processed commodity tolerances.

GLN 860.1480: Meat, Milk, Poultry, Eggs

Page 11; Paragraph 3; Line 5

EPA statement:

"The calculation of the maximum dietary is tentative ...".

Aventis' comment:

Add the word "burden" to the statement "The calculation of the maximum dietary (**burden**) is tentative ...".

Page 11; Paragraph 4; Lines 1-2

EPA statement:

"...tolerances for residues of carbaryl *per se* in livestock (excluding swine) commodities should be reassessed ...".

Aventis' comment:

The tolerance expression in GLN 860.1480 should be modified to agree with the one in GLN 860.1300 (page 4): "... tolerances for ruminant meat and milk should be expressed as residues of free and conjugated carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, and 5-methoxy-6-hydroxy carbaryl."

Tolerance Reassessment Summary

Table C. Tolerance Reassessment Summary for Carbaryl

Tolerance Listed Under 40 CFR §180.169(a); Page 79

Aventis' comment:

Under the commodity "Corn, forage", Comments on "Corn, sweet, forage": should read "Residue data indicate that the tolerance for sweet corn forage should be increased." (i.e., replace "field" with "sweet" in sentence).

Miscellaneous Typographical Errors

- Under "REGULATORY BACKGROUND", paragraph 3 of section, line 5 (page 2): remove "on" from the sentence "... should not delay on the reregistration ...".
- Under "SUMMARY OF SCIENCE FINDINGS, GLN 860.1500: Crop Field Trials", paragraph 4, line 5, page 7: remove period (.) after "ppm" in "... current tolerance of 10 ppm.and all residue data ...". Also in memorandum, page 3, paragraph 1.
- Under "SUMMARY OF SCIENCE FINDINGS, GLN 860.1520: Processed Food/Feed", paragraph 2, line 2 (page 9): add "to" to the statement "... when this concentration factor is applied (to) the HAFT residue ...".
- Footnotes to Table B. Residue Chemistry Science Assessment for Reregistration of Carbaryl: #38: correct the spelling of "canceled".
- Table C. Tolerance Reassessment Summary of Carbaryl, under the commodity "Sorghum, stover" (under "Comments": correct spelling of sorghum).

PC Code No. 056801; Case 0080

Revised EFED Risk Assessment of Carbaryl in Support of the Reregistration Eligibility Decision (RED)

- Phase 1 Error Correction -

July 12, 2002

Aventis CropScience P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709

Revised EFED Risk Assessment of Carbaryl in Support of the Reregistration Eligibility Decision (RED)

- Phase 1 Error Correction -

TABLE OF CONTENTS

TABLE OF CONTENTS	2
ENVIRONMENTAL FATE AND ECOLOGICAL RISK ASSESSMENT FOR THE REREGISTRATION OF CARBARYL	3
General	3
1.0 Summary and Environmental Risk Conclusions	3
Fate and Water Assessment	3
3.0 Integrated Risk Characterization	3
Introduction.	
4.0 Environmental Fate Assessment	4
Exposure Characterization	4
5.0 Drinking Water Assessment	5
Drinking Water Modeling	5
Appendix D: Toxicity Assessment	
Toxicity to Terrestrial Animals	

Environmental Fate and Ecological Risk Assessment for the Reregistration of Carbaryl

General

Several References Throughout the Document

EPA statement:

The company name of the registrant is listed throughout the document as Aventis Corporation, Aventis Crop Sciences, Aventis Crop Science, and Aventis Crop Science Corporation.

Aventis' comment:

Reference should be either to Aventis or Aventis CropScience.

1.0 Summary and Environmental Risk Conclusions

Fate and Water Assessment

Page: 4 Paragraph: 1 Line: 16

EPA statement:

...to those reported n non-targeted...

Aventis' comment:

extra "n" in sentence

3.0 Integrated Risk Characterization

Introduction

Page: 8 Paragraph: 1 Line: 8

EPA statement:

alkaline (pH half-life = 5 hours environments.

Aventis' comment:

alkaline (pH half-life = 3.2 hours) environments.

half-life is 3.2 not 5 hours as noted elsewhere in the document. Missing closing parenthesis.

4.0 Environmental Fate Assessment

Exposure Characterization

Page: 17 Paragraph: 3 Line: last sentence

EPA statement:

Detailed discussion and reviews (DERs) of the studies that are included in this assessment are attached in Appendix A.

Aventis' comment:

It is inappropriate to include the DERs in the RED. A sufficiently detailed summary of study findings is already included in the EFED Chapter. The summary of endpoints that is included in the draft Carbaryl EFED Chapter is typical of other Draft EFED REDs that have been issued recently and provides sufficient information to allow the reader to determine the endpoints that were selected for modeling and the justification for their selection. The inclusion of the more detailed information present in the DERs is unnecessary.

We have reviewed the dockets for many of the RED documents that have recently been issued (many other insecticides and several fungicides) and none of them include DERs in any of the preliminary Environmental Fate and Effects Assessments. DERs should be made available to the public through the regular procedure under the Freedom of Information Act after they have been reviewed and cleared for confidential business information. The inclusion of the DERs in the docket that is publicly available circumvents this process and is a departure from the procedures that have been followed until now by the Agency. It is unclear why the Agency chose to change their policy for only certain DERs for a single product when adequate summary information is already provided in the text of the Carbaryl EFED Chapter.

Page: 17 Paragraph: 4 Line: 4

EPA statement:

lower levels (generally less than 0.01 μ/L).

Aventis' comment:

value missing units - (generally less than 0.01 µg/L).

Persistence

Microbially-Mediated Processes

Page: 22 Paragraph: 2 Line: 1

EPA statement:

A number of soil microorganisms

Aventis' comment:

"microorga nisms"

5.0 Drinking Water Assessment

Drinking Water Modeling

Page: 33 Table 6

EPA statement:

Crop name – Sugar Beats (MN)

Aventis' comment:

Correct spelling is Sugar Beets

Appendix D: Toxicity Assessment

Toxicity to Terrestrial Animals

Mammals, Acute and Chronic

Page: 237 above Table 4

EPA statement:

"Although at this time two-generation rat reproduction study data are not available, ..."

Aventis' comment:

A two-generation rat reproduction study has been submitted and found to be acceptable by the Agency (MRID# 45448101).